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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,763	09/17/2001	Paul J. Thompson	11576.51US11	8878
21127	7590	06/27/2005	EXAMINER	
KUDIRKA & JOBSE, LLP ONE STATE STREET SUITE 800 BOSTON, MA 02109			WEBB, SARAH K	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/954,763

Applicant(s)

THOMPSON ET AL.

Examiner

Sarah K Webb

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 23, 25, 26 and 28-36 is/are pending in the application.
- 4a) Of the above claim(s) 9, 12, 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11, 13, 14, 17-21, 23, 25, 26, and 28-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 25 is objected to because of the following informalities: "said inner tube" in line 6 should be changed to "said inner tubular member" in order to correspond with the limitation in line 3. Appropriate correction is required.

Response to Arguments

2. Applicant's arguments with respect to the rejections under Mische have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 first states that the inner and outer catheters are slidable relative to one another. Claims 17 and 18 then require a thermal bonding surface that fixedly couples the inner and outer catheters together. The catheters cannot be both slidable and fixed at the same time, so these claims are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 32 is rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,168,617 to Blaeser et al.

Blaeser discloses a catheter with a stent (48) mounted on a distal region of a shaft (14) and a retractable sheath (28). Figure 4 shows that apertures (52) may be formed in the outer sheath (column 6, lines 9-10), and a port (60) is in communication with a passageway in the catheter and the apertures of the outer sheath (column 5, lines 30-32 and 50-54).

5. Claims 1-8,10,11,13,14,17-19,23,and 33-36 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,786,918 to Krivoruchko et al.

'918 discloses a catheter that includes an outer shaft (26), inner shaft (24), fluid channel (68A-H), admission port (shown in Figures 3 and 15), stent (28) mounted on the distal region, and a spacer (62) comprising a plurality of "splines" disposed in the fluid channel. The spacer (62) can best be seen in cross-section in Figure 5 and is substantially similar to the spacer shown in Figure 5 of the application. Figure 2 illustrates that the spacer (62) extends a majority of the length of the catheter shafts (24,26). '918 discloses that the inner and outer shafts are slidable relative to one another (column 3, lines 35-37). '918 also explains that the lumens of the device can be flushed with saline during use by way of luer fitting (44) and handles shown in

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Figures 3 and 15 (column 6, lines 12-20). This is considered to meet the limitations of admission port and fluid channel. As shown in Figure 2, a guide wire (82) may be disposed in the lumen of the inner shaft (24) (column 6, lines 13-14). The stent (28) is self-expanding and deployed by retraction of the outer shaft (26).

Regarding claims 17 and 18, the spacer is considered to have a surface that is *capable of* being thermally bonded to another surface. No other structural characteristics are required by these claims. As discussed above, fixedly coupling the inner and outer shafts together contradicts the limitation in claim 1 that they are slidable relative to one another.

Regarding claims 20 and 21, the outer tubular shaft (26) has a "discharge opening" at its distal end (40) that is in communication with the fluid channel (68). The claims do not require the opening be in the shaft wall, so the opening at the distal end of the shaft meets this broad claim language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 25, 26, and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,129,700 to Fitz in view of Blaeser et al.

As clearly illustrated in Figure 5 of Fitz, the device includes an outer tubular member (22), inner tubular member (16), fluid channel (24) between the outer and

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inner tubular members, and stent (14) mounted on the distal end of the inner tubular member (16). It is inherent from the disclosure that a port in communication with the fluid channel (24) is included to provide fluid to the channel (24).

A discharge opening (54), or "fluid exchange aperture", at the distal end of the outer tubular member (22) allows fluid to flow from the fluid channel (24) to a patient's lumen (column 4, lines 25-35). There is a plurality of such apertures (54), and the apertures (54) are located on the portion of the outer tubular member (22) covering the stent. The stent is self-expanding (column 3, line 41) and is deployed by retracting the outer tubular member (22) (column 4, line 64), as shown in Figure 7. The inner tubular member (16) is hollow and defines a guide wire lumen (18).

Fitz fails to include fluid exchange apertures at both the proximal and distal ends of the stent. As discussed above, Blaeser shows that it is known in the art to provide apertures in an outer sheath over the length of a stent mounting region. Blaeser teaches that the apertures can enhance flexibility (column 6, lines 9-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include apertures at both ends of the stent mounting region of the Fitz device, as Blaeser teaches that apertures can enhance flexibility. Further it has been held that a mere duplication of a part of a device involves only routine skill in the art.

7. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fitz in view of US Patent No. 5,005,584 to Little.

Fitz includes all the limitations of claim 30, except for a pressure measuring device. Little discloses a guide wire that measures fluid pressure and is capable of being used with the Fitz device. It would have been obvious to one of ordinary skill in

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the art at the time the invention was made to substitute the Little guide wire for the guide wire of Fitz, as this produces a combination that is capable of measuring fluid pressure within a passageway. This combination would be provide the operator with the capability of detecting defects in the body passageway.

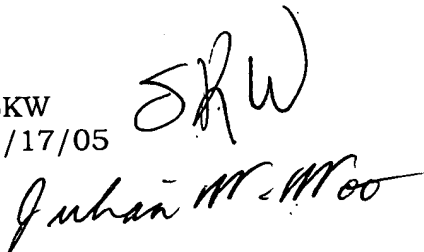
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
6/17/05



JULIAN W. WOO
PRIMARY EXAMINER